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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,526

01/23/2007

Judith Boston

9618a

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7590

02/10/2009

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

02/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,526	<b>Applicant(s)</b> BOSTON, JUDITH	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 89-132 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89-132 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Examiner notes that the Applicant did not correct the preliminary amendment (3/31/2006) to the Specification as required in the Notice of Non-Compliant Amendment attached to the previous Office Action (4/8/2008). As such, the preliminary amendment (3/31/2006) has not been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Specification does not enable methods of medical treatment and compositions for medical treatment containing tetrameric oxygen (O<sub>4</sub>).

#### *The nature of the invention:*

The invention is directed to method of using as a medical treatment and compositions for use in medical treatment containing tetrameric oxygen (O<sub>4</sub>).

#### *The state of the prior art and the predictability or lack thereof in the art:*

There does not appear to be any prior art directed to the use of tetrameric oxygen (O<sub>4</sub>) as claimed. Further, there is insufficient evidence to establish that O<sub>4</sub> exists, much less be prepared and/or isolated. At most, the existence of O<sub>4</sub> has been theorized, however, the disclosed stability

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is in the realm microseconds. As such, even if O4 does exist, because the molecule would only exist for microseconds, there does not appear to be any practical method of preparing a composition which can be used to treat a given condition. See Schroder, pp. 573-574.

*The amount of direction or guidance present and the presence or absence of working examples:*

The Specification alleges that there is a product containing O4 in an aqueous solution, however, said assertion is suspect in view of the above.

*The breadth of the claims and the quantity of experimentation needed:*

The claims are broad in that they claim the use of tetrameric oxygen. As such, in light of the above, one of ordinary skill in the art would be required to do undue experimentation in order to show that O4 exists and prepare compositions that would enable O4, if it does exist, to be stable enough to be used in medical treatment.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant has argued that there is evidence of the presence of O4 in the aqueous solution and that the O4 containing solution increases transcutaneous oxygen levels. However, such evidence must be submitted by way of affidavit or declaration under 37 CFR 1.132 containing factual evidence such as what is contained in the solution, other than the alleged O4, how the experiment was performed, and the data obtained, preferably supported by documentation such as lab notes, data, etc.. There is no indication as to how Dr. Xu arrived at the conclusion that there was the presence of a molecule having a molecular weight of 64 and that said molecule was O4. The mere fact that the alleged molecule had a molecular weight of

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64 is not sufficient to conclude that the molecule was O<sub>4</sub> as there is no evidence that other substances having a molecular weight of 64 were excluded by the experiment. Also, there is no indication that Dr. Xu conducted experiments as to the stability of the alleged O<sub>4</sub> molecule.

There no indication that the tests performed showed that O<sub>4</sub> was present in solution for up to three years. The arguments only indicate that oxygen was present for 3 years but does not indicate that tests were done showing that the particular species of oxygen, O<sub>4</sub>, was present for 3 years. Furthermore, there is no indication from the Specification or arguments as to how O<sub>4</sub> was prepared in the aqueous solution. Enablement requires that the Specification teach one of ordinary skill in the art how to make O<sub>4</sub> in stable form so as to be able to exist in an aqueous solution as the art above indicates that O<sub>4</sub> if it exists is only stable to the extent of microseconds.

There is no indication that the transcutaneous oxygen monitor has the ability to measure the presence of O<sub>4</sub>. As such, the data provided does not show that O<sub>4</sub> was the cause of the difference as opposed to O<sub>2</sub> is normally found dissolved in water. The transcutaneous oxygen monitor measures the amount of oxygen emanating from the skin. Obviously if you place an aqueous solution containing oxygen on the skin you are going to measure more oxygen than you would without the presence of said solution as the monitor will measure the oxygen emanating from the solution in addition to the amount of oxygen emanating from the skin. However, this provides no evidence that said aqueous solution contains O<sub>4</sub> or that said solution can therapeutically increase the amount of oxygen in the tissue. Since the transcutaneous oxygen monitor does not provide evidence that the aqueous solution contains O<sub>4</sub> or that said solution can therapeutically increase the amount of oxygen in the skin, the assumption that application of the

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solution to other tissue would result in the localized increases in partial pressure of oxygen is amounts to speculation which is not sufficient to enable the claimed invention.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
February 10, 2009

/John Pak/  
Primary Examiner, Art Unit 1616